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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/584,742 | 04/23/2007 | Toshio Hirano | SPO-128 | 5794 |
| 23557 7590 05/09/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950 | | | | |
| EXAMINER SHIN, DANA H | | | | |
| ART UNIT 1635 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/584,742

Applicant(s)

HIRANO ET AL.

Examiner

DANA SHIN

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 and 13-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3(a)-(c), 8-10(a)-(c), 15(A)(a)-(c), 15(C)(a)-(c), drawn to a regulatory agent of Snail activity encoding a protein or an EMT-inducing agent comprising an isolated DNA encoding LIV1.

Group II, claim(s) 1-3(d), 4, 6-7, 11, 13, 15(A)(d), 15(C)(d), 16 drawn to a regulatory agent of Snail activity hybridizing with a DNA sequence, an agent for suppressing Snail activity, or an EMT-suppressing agent comprising an antisense oligonucleotide or a double-stranded RNA against a nucleic acid encoding LIV1.

Group III, claim(s) 14, drawn to a method of screening for a candidate substance for an agent for suppressing Snail activity.

Group IV, claim(s) 15(B)(a)-(d), 15(D)(a)-(d), drawn to a wound healing agent comprising a regulatory agent of Snail activity or an EMT-inducing agent, wherein the agent is an isolated protein encoded by a DNA.

Group V, claim(s) 17, drawn to a regulatory agent of a protein activity that requires zinc comprising a protein comprising the amino acid sequence of LIV1 and variants thereof.

In addition to electing a single inventive group as indicated above, applicant is further required to elect a single disclosed SEQ ID NO.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of groups I-V are found to have no special technical feature that define a contribution over the prior art of Van Doren et al. (applicant's citation R3). The first claimed invention in the instant application is an agent comprising a DNA (SEQ ID NO:4) that encodes a LIV1 protein (SEQ ID NO:2). Van Doren et al. taught DNA encoding human LIV1 protein, which functions to regulate gonad morphogenesis. Therefore, applicant's inventions claimed in the instant application do not contribute a special technical feature when viewed over the prior art. Accordingly, the inventions of groups I-V do not have a single inventive concept and so lack unity of invention, thus restriction for examination purposes as indicated is proper.

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed agents comprising any one of SEQ ID NOs:1-42, the Marksuh group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity and

(B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant agents are considered to be each separate invention for the following reasons:

The agents do not meet the criteria of (A), common property or activity or (B)(1), common structure or (B)(2), art recognized class of compounds. Each agent behaves in a different way in the context of the claimed invention because the claimed agents target different and specific mRNA or protein regions of LIV1 and therefore exert differing degrees of biological effects. Hence, each member of the agents cannot be substituted one for the other, with the expectation that the same intended result would be achieved. Further, there is no common structure shared by all of the alternatives because each SEQ ID NO comprises different nucleotides or amino acids not shared by another. Accordingly, unity of invention among the agents of different SEQ ID NOs is lacking and each agent claimed is considered to constitute a special technical feature.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Applicant is required to elect a single inventive group and a single disclosed SEQ ID NO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635